

REMARKS

Upon entry of the present amendment, claims 53-89 will be pending (claims 1-52 having been canceled and new claims 53-89 added). The new claims are supported by the specification and the claims as originally filed. Specifically, new claims 53 and 87-89 are supported by the specification at, *e.g.*, page 5, line 22 to page 6, line 4; and page 24, lines 3-8. New claim 54 is supported by the specification at, *e.g.*, page 6, lines 12-19. New claims 55 and 56 are supported by the specification at, *e.g.*, page 5, lines 7-13. New claims 57 and 58 are supported by original claim 3. New claims 59-63 are supported by the specification at, *e.g.*, page 27, lines 17-21. New claims 64-86 are supported by the specification at, *e.g.*, page 24, line 3, to page 27, line 16. No new matter has been added.

Restriction Requirement

Applicants' representatives thank Examiner Zeman for the telephone conference held on July 11, 2006, to discuss the Restriction Requirement outstanding in the present application.

In response, Applicants elect Group I (claims 6-9, 10-12 and 42). Applicants have canceled all of the pending claims and present new claims 53-89, which fall within Group I. Applicants "further elect" nucleoprotein as the antigen and hsp60 as the stress protein.

The election is made with traverse.

Applicants respectfully request that the Examiner revise the present requirement so that the claims remain divided between Group I and Group II but that the "further restriction" of Group I be withdrawn. As currently set out in the Office action, the subject matter of Group I is further divided so the vaccine Applicants invented and wish to claim can only include a single polynucleotide (Office action at page 2). If the Examiner determines, after considering the remarks that follow, that examining more than a vaccine containing only a single polynucleotide would be burdensome, Applicants ask that the further division be made as a species election (with the elected species being nucleoprotein and hsp60).

In setting out the "Sequence Election Requirement", the Examiner states, "Applicant must further elect a single SEQ ID NO. (See MPEP 803.04)." That section of the MPEP is not,

however, well suited to the present case. The cited section describes “polynucleotide molecules *defined by their nucleic acid sequence*” (emphasis added). In keeping with that, the three examples provided of nucleotide sequence claims recite “an isolated and purified DNA fragment” or “a combination of DNA fragments”. Further, all of the exemplary claims recite SEQ ID Nos., and all cover at least 1,000 sequences. Here, Applicants claim a vaccine. Granted, the vaccine includes a polynucleotide -- a polynucleotide encoding an influenza antigen and a heat shock protein (hsp), both of which are recited in the present claims with particularity. The polynucleotide is not defined by its nucleic acid sequence but rather by the novel combination of proteins it encodes. No SEQ ID Nos. are recited in the present claims. The sequences are not new. It seems quite clear that the MPEP, at 803.04, is specifically intended to provide guidance where Applicants claim a large number of new sequences. That direction should not be applied to the present invention.

Even if the MPEP at 803.04 were followed, that section recognizes the Office's commitment to “aid the biotechnology industry in protecting its intellectual property” by permitting “a reasonable number of such nucleotide sequences to be claimed in a single application”. Normally, ten sequences constitute a reasonable number. MPEP 803.04. In view of this, if the Examiner will not withdraw the “further division” or reinstate the “further division” as a species election, Applicants respectfully request that the “further division” be redrawn to allow election and examination of vaccines containing at least one of ten polynucleotides. As seven influenza antigens are recited in new claim 53, Applicants respectfully suggest a division that encompasses these seven antigens and a single hsp (seven sequences).

Applicants appreciate the Office's position that Examiners should not be unduly burdened. For the reasons that follow, Applicants believe that a search for material relevant to all of the subject matter of Group I can be readily made. If the search and examination of all the claims in an application can be made without serious burden, the Examiner must examine them on the merits, even though they include claims to independent or distinct inventions. MPEP 803. Using the search function of the U.S. Patent and Trademark Office's website, Applicants' representatives searched the specifications of all issued U.S. patents with the following query:

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Client's Reference No.: SP-9 US CIP-DIV

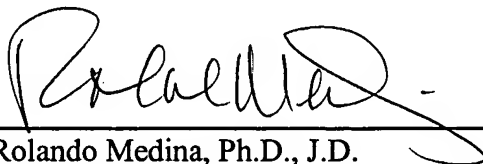
spec/(vaccine and (influenza and hsp)). The query identified 164 patents. Some of those, and possibly many of those, would not be available as prior art to the present application. Similarly, PubMed (<http://www.ncbi.nlm.nih.gov/>) was searched with the query "vaccine influenza hsp" and only one publication, which was published about three years after the priority date of the present application, was identified. A second search of the PubMed database with the query "influenza hsp" identified 17 references. It is not Applicants position that these inquiries have identified all of the prior art that should be reviewed for relevance, but it would seem to indicate that a more than adequate search could be performed for the subject matter now claimed without undue burden.

Finally, Applicants note that, should the present division be maintained, they would have to file well over 100 applications to cover the subject matter presently claimed, which is only that of Group I. Applicants cannot see how that can be in the best interest of the public or the Office

Enclosed is a Petition for Extension of Time along with the required fee. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney's Docket No. 12071-011004.

Respectfully submitted,

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